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DIVISION OF PROFESSIONAL REGULATION

PUBLIC MEETING NOTICE:	CONTROLLED SUBSTANCE COMMITTEE
DATE AND TIME:	Wednesday, August 25 at 9:00 a.m.
PLACE:	Buena Vista, Dining Room, 661 S. DuPont Highway, New Castle, Delaware 19720
APPROVED:	December 1, 2010

MEMBERS PRESENT

Michael Kremer, DMD, Dental Representative, President
Luis Garcia, Jr., DPM, Podiatric Representative, Vice President
Philip Kim, M.D., Medical Representative (10:00)
Ann Dominick, APN, Nursing Representative
Howard Simon, R.Ph, Pharmacy Representative
Bonnie Wallner, R.Ph., Pharmacy Representative
Stephen Ruggles, PA-C, PA Representative
David W. Dryden, R.Ph., J.D., Director Office of Controlled Substances

MEMBERS ABSENT

Robert Flanagan, DVM, Vet Representative
Mark Hanna, Public Representative

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

Patricia Davis-Oliva, Deputy Attorney General
Judy Letterman, Administrative Specialist

ALSO PRESENT

Jean Chiquoine
Philip Reed
Cheryl Heiks
Steven Dettwyler
Bruce Divincenzo

CALL TO ORDER

Dr. Kremer called the meeting to order at 9:15 a.m.

REVIEW AND APPROVAL OF MINUTES

A motion was made by Dr. Kremer, seconded by Mr. Garcia, to accept the minutes as presented. The motion was unanimously carried.

PRESIDENT'S REPORT

Dr. Kremer stated that he was asked yesterday if he could grant a continuance for the hearing that was scheduled for today for Renaissance Pharmacy. He granted the continuance because both parties requested it, but Dr. Kremer is very concerned with continuances for hearings being requested less than a week before the meeting date. The professional members have to clear their calendars to take off on these days and if the hearings are cancelled at the last minute, it is difficult to reschedule patients.

Due to the increased need for disciplinary hearings regarding controlled substance registrations, it has been recommended by the Secretary of State that the Committee have hearing panels. Mr. Dryden suggested that there be panels of alternating three Committee members that attend at a time instead of the whole Committee having to attend each hearing. Members will try to be assigned according to specialty. Meetings will be held on months when the Committee does not meet. Hearing panels will convene on Wednesdays at the Governor Bacon facility when possible.

A recommendation was also made for the Committee not to use a complaint person since all the Board is empowered to do is revoke or suspend registrations. If a professional member is needed for consultation, a contact person can be assigned.

Mr. Dryden suggested that he could be the primary contact person for the committee so that no one will have to be recused from the hearings, unless they were also consulted. The Committee agreed.

UNFINISHED BUSINESS

Reviewing and Signing of Pollock Order

The Board signed the Decision and Order for William Pollock, MD

Review of Kerner Order

The Board reviewed an emergency suspension order issued by Secretary Bullock suspending the controlled substance registration of Dr. Jeffrey Kerner. This emergency suspension order will be signed by Secretary Bullock today and effective immediately.

A motion was made by Dr. Kremer, seconded by Dr. Garcia to accept this Order. The motion unanimously carried.

NEW BUSINESS

Registrant Application Reviews

There were no applications that needed review.

Hearing for Michele Gillespie

This hearing was not held because Ms. Gillespie signed a consent agreement.

DIRECTORS REPORT

Mr. Dryden reported that there had been a great deal of activity concerning controlled substances in the General Assembly pertaining to the Prescription Monitoring Program and the Attorney General's Bill on Title 16.

There have been 28 robberies of pharmacies in Delaware this year and this is a great concern. The Division of Professional Regulation, DEA, Board of Pharmacy, State Police, and the Department of Health and Social Services are working on ways to increase the security in pharmacies inside and outside. Security in pharmacies will include but not be limited to:

- A secure, metal safe that meets the safe requirements as specified in Controlled substance Regulation 5.1.1.1
- The installation of motion detectors with floor to ceiling coverage of where drugs are accessible in the pharmacy department.
- Camera surveillance equipment with coverage of at least 7-15 frames per second of all public accessible areas including counters, counseling areas, entrance doors within the pharmacy department as well as outside coverage which can provide better identification of assailant activities.
- Floor to ceiling gating, walls, etc. which will limit the possibility of intruder access to the pharmacy during non-working hours.
- Back-up alarm and electrical systems which will notify security of a loss of power and potential diversion.

Mr. Dryden stated that there is a nation-wide drug disposal on September 25, 2010, sponsored by the DEA. The DEA is present today to discuss the details with the Committee.

COMMITTEE REPORTS

Medical Examiner's Report

There was no report.

DEA Report – Philip Reed

Mr. Reed stated that there will be a national drug take-back event held on September 25, 2010. Delaware will have several stations set up. The disposal will be for tablets and capsules only and will not include injectables, aerosols or liquids.

Mr. Reed explained the process and that public notices will be sent out.

Substance Abuse Report

No report.

Law Enforcement Report

Chief Agent DiVincenzo reported that their office has been very active in investigating controlled substance diversion. He stated that he wished to address several issues regarding improving public health and welfare. The first item was the concern about the requirement for IDs for inmates. He explained the issue and recommended a solution. The public can call the Office of Narcotics and Dangerous Drugs (ONDD) to ask questions or voice concerns anonymously. The

second item he addressed was the security issues in pharmacies. He suggested that a cut-off time be enforced. He also asked the Committee to revisit the issue of requiring a back-up system for the alarms.

Regulatory Committee

Mr. Dryden reported that when the Committee last met, it discussed regulation amendments. Ms. Davis-Oliva will draft regulations. She will bring a final draft to the next meeting.

Legislative Committee

Mr. Dryden reported that the prescription-monitoring program bill passed. The Office of Controlled Substances is now waiting on funding in order to initiate the program.

INSPECTION REPORT

There was no report.

COMMITTEE CORRESPONDENCE

None

OTHER BUSINESS BEFORE THE BOARD

Dr. Garcia asked about the duty to report diversion.

PUBLIC COMMENT

Secretary of State, Jeffrey Bullock and James Collins, Division of Professional Regulation (DPR) Director and Deputy Secretary of State were in attendance to speak with the Committee. He first explained the history of the Buena Vista Center and that the state has plans to renovate the house as well as utilize the 250 acres of land.

Secretary Bullock thanked the members for volunteering their time to be on this Committee. He recognized that the Committee is made up of professionals such as pharmacists, doctors, and dentists. He asked for the Committee's help to make recommendations when they see a need or an issue in processing arise. He advised the Committee that DPR has received a lot of good and bad attention lately regarding the Bradley case. As a result of this tragic incident, many things have been learned and new procedures, laws, and rules have been enacted in order to better protect the public. New legal resources are available and cases are now able to be expedited.

Mr. Collins advised that he is meeting with several organizations to address the security issues and hiring one or two pharmacists/inspectors. He advised that he would like to establish standards with the Board of Medical Practice first, and then apply it to other professions. He spoke about the tamper-proof prescription pads and the prescription monitoring program to help identify doctor shoppers.

Dr. Kim recommended that anonymous reporting be allowed so that reporting on other doctors will be more open. He also brought up the fact that insurance carriers and pharmacies already have some programs in place; however, there can be gaps in the records.

NEXT SCHEDULED MEETING

The next meeting will be held on Wednesday, December 1, 2010 at 10:00 a.m.

Adjournment

A motion was made by Dr. Kremer, seconded by Dr. Ruggles, to adjourn the meeting. The motion unanimously carried. The meeting adjourned at 11:00 a.m.

Respectfully submitted,

David W. Dryden, R.Ph., Esq.